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| 10/797,663 | 03/09/2004 | Michael E. Daniels | 4001-0018B (ZM0602) | 3929 |
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| ALEDO, TX 76008 | | | | |
| EXAMINER | | | | |
| RAMANA, ANURADHA | | | | |
| ART UNIT | | | PAPER NUMBER | |
| 3733 | | | | |

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/797,663

Applicant(s)

DANIELS, MICHAEL E.

Examiner

Anu Ramana

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 August 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/26/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the torx shaped portion of claims 10 and 15 must be shown or the feature canceled from the claims. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement-drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the examiner does not accept the changes, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities. On page 10, para [0020], "torqx" should be "torx" to correct a minor typographical error.

Appropriate correction is required.

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Claim Objections

Claims 10 and 15 objected to because of the following informalities. In line 2 of each of claims 10 and 15, it appears that "torqx" should be "torx" to correct a minor typographical error. Appropriate correction is required.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101, which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 22 and 23 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 33 and 34 of copending Application No. 10/993,661. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 5-6 and 8-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-11 and 14-22, of copending Application No. 10/993,661.

Claims 1, 2 and 4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 7 of copending Application No. 10/993,661.

Claim 19 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over each of claims 28, 31 and 32 of copending Application No. 10/993,661.

Claims 22 and 23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over each of claims 37 and 41 of copending Application No. 10/993,661.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the claims of the present application and the claims of the copending application is that the claims of the copending application include many more elements and are thus more specific. Thus the invention of the claims of the copending application is in effect a "species" of the "generic" invention of the claims of the present application. It has been held that the generic invention is "anticipated" by the "species." See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since the claims of the present application are anticipated by the claims of the copending application, they are not patentably distinct from the claims of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 7, 17 and 18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12, 23 and 25 of copending Application No. 10/993,661 in view of McCue et al. (US 6,506,216).

Claims 12, 23 and 25 of 10/993,661 disclose all elements of the claimed invention except for an included angle of about 180 degrees between the keel-like portions.

McCue et al. teach providing wing elements or "keel-like portions" on the keel or "base" 24 of a tray or "plate" 12 at varying angles (Fig. 2 and col. 3, lines 29-36).

It is also noted that Applicant has not disclosed a criticality to the angle between the keel-like portions (page 9, lines 7-8).

Accordingly, it would have been an obvious matter of design choice to a person of ordinary skill in the art to provide the keel-like portions in the implant of 10/993,661 at an angle of about 180 degrees because Applicant has not disclosed that providing a specific angle between the keel-like portions provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the implant of 10/993,661 and applicant's invention, to perform equally well with either the angle taught by 10/993,661 or the claimed "about 180 degrees" because both angles would perform the same function of fixing the tibial plate to the proximal tibia.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

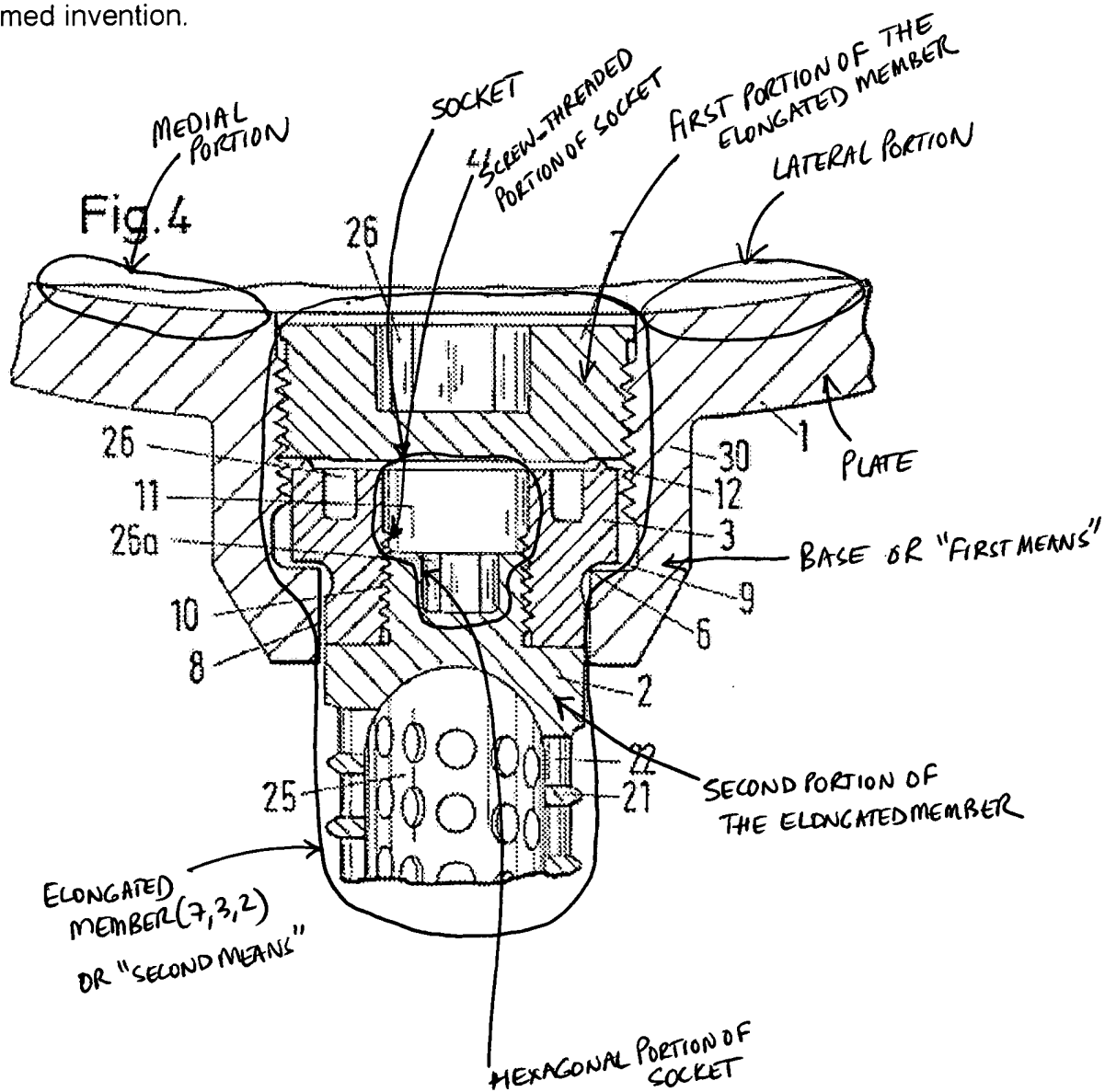
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

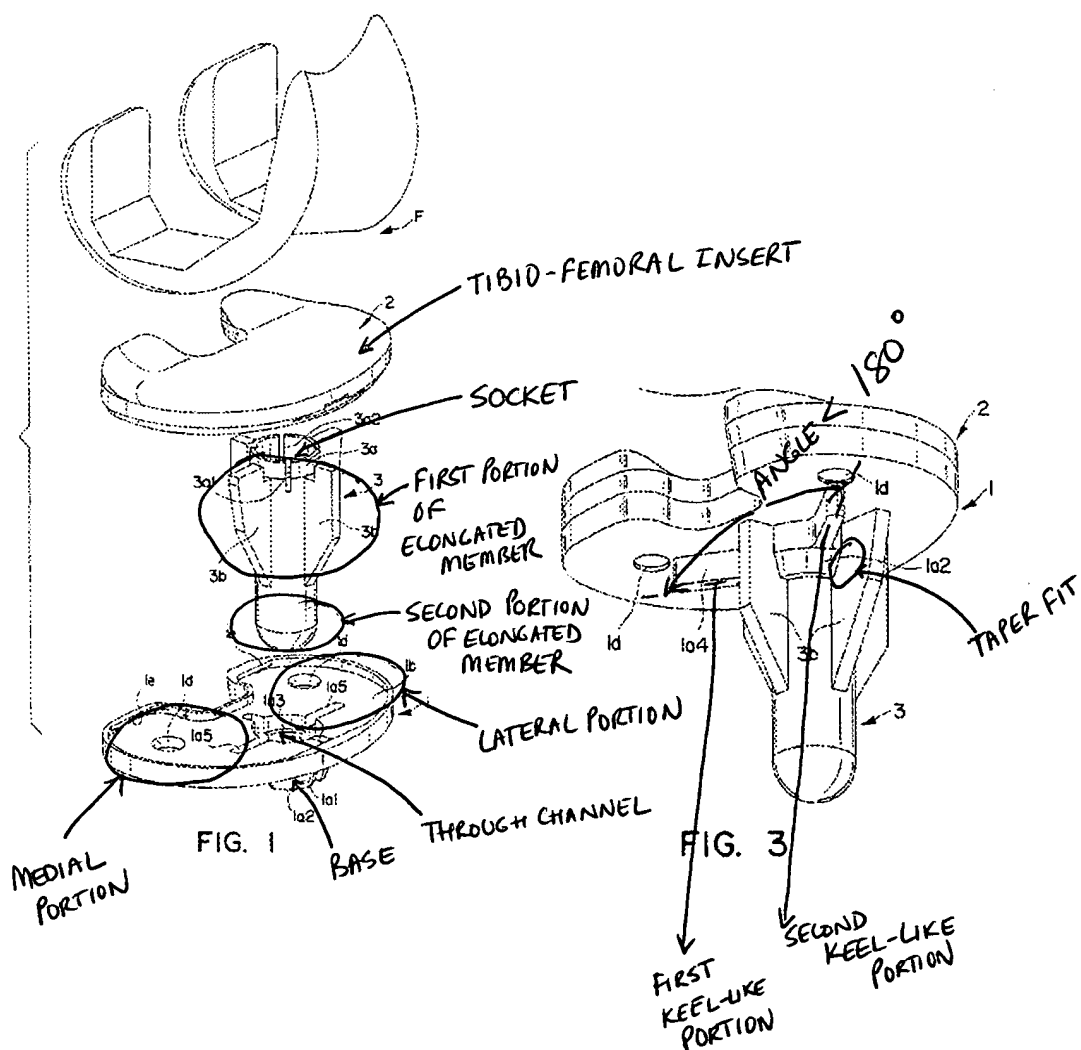
Claims 1, 3, 4, 8-11 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Sutter et al. (US 6,102,951).

Sutter et al. disclose a tibial implant apparatus including: a shell or "plate" 1; a projection or "base" or "first means" 30 extending from the tibial plate; an anchoring element or "elongated member" or "second means" (7, 3, 2) including a first portion 7 and a second portion 2; a through passage or "channel" in the tibial plate and the base wherein the through-channel removably receives a first portion 7 of the elongated member from a point superior to tibial plate 1 and the second portion 2 of the elongated member extends away from base 30 (Fig. 4, col. 1, lines 17-23, col. 2, lines 31-55, and col. 3, lines 41-56). See Fig. 4 from Sutter et al. below, marked up to show elements of Applicant's claimed invention.



Claims 1-6, 8-9, 11-14 and 19-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Delfosse (US 5,658,341).

Delfosse discloses a tibial implant apparatus including: a tibial socket or "plate" 1 having medial and lateral portions 160; a base 1a1 extending from the tibial plate; a stabilizing pin or "elongated member" 3 including a first portion and a second portion; a through passage or "channel" 1a in the tibial plate and base wherein the through-channel removably receives a first portion of the elongated member from a point superior to tibial plate 1, and the second portion of the elongated member extends away from the base; a tibial plate or "tibio-femoral insert" 2 coupled to the tibial plate 1 (Figs. 1 and 3, col. 2, lines 34-67 and col. 3). Also see Figs. 1 and 3 of Delfosse marked up below to illustrate features of Applicant's invention.



Regarding claims 5 and 12, Delfosse discloses base 1a2 to have first and second keel-like portions or "protuberances" 1a4 that extend radially outwardly relative to the through channel (col. 2, lines 50-51 and marked up Fig. 3 above).

Regarding claims 8 and 13, Delfosse discloses first portion of elongated member 3 to be removably retained in the through channel by a taper fit.

Regarding claims 9 and 14, the elongated member 3 has a cone-shaped internal counterboring or "socket" 3a2.

Regarding claims 19-20, as previously discussed Delfosse discloses a tibial plate 1, keel-like portions or "first means" 1a4 for rotational fixing of plate 1 relative to the proximal tibia and a stabilizing pin or "second means" for linearly fixing plate 1 to the proximal tibia.

The method steps of claims 22 and 23 are inherently performed when the Delfosse tibial plate 1 is positioned on a proximal tibia by means of base or "first member" 1a1 followed by introduction of stabilizing pin or "second member" 3 through recess 1a and firmly attaching member 3 to plate 1 and the proximal tibia (col. 3, lines 10-27).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sutter et al. (US 6,102,951) in view of Delfosse (US 5,658,341).

Sutter et al. disclose all elements of the claimed invention except for a tibio-femoral insert coupled to plate 1.

Delfosse teaches providing a "tibio-femoral" insert 2 coupled to a tibial plate to cooperate with (i.e., provide an articulating surface for) the femoral component of a total knee prosthesis (Fig. 1 and col. 2, lines 34-40).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a tibio-femoral insert coupled to the plate in the Sutter et al. implant, as taught by Delfosse, in order to mate the implant of the combination of Sutter et al. and Delfosse with the femoral component of a total knee prosthesis.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Delfosse (US 5,658,341) in view of McCue et al. (US 6,506, 216).

Delfosse discloses all elements of the claimed invention except for an explicit reference to the angle between the first and second keel-like portions to be "about 180 degrees." See marked up Fig. 3 of Delfosse on page 7 of this action suggesting an angle less than 180 degrees between the first and second keel-like portions.

McCue et al. teach providing wing elements or "keel-like portions" on the keel or "base" 24 of a tibial tray or plate 12 at varying angles (Fig. 2 and col. 3, lines 29-36).

It is also noted that Applicant has not disclosed a criticality to the angle between the keel-like portions (page 9, lines 7-8).

Accordingly, it would have been an obvious matter of design choice to a person of ordinary skill in the art to provide the first and second keel-like portions in the Delfosse implant at an angle of about 180 degrees because Applicant has not disclosed that providing a specific angle between the first and second keel-like portions provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the Delfosse implant and applicant's invention, to perform equally well with either the angle taught by Delfosse or the claimed "about 180 degrees" because both angles would perform the same function of fixing the tibial plate to the proximal tibia.

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Claims 10, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delfosse (US 5,658,341).

Delfosse discloses elongated member 3 to have a cone-shaped socket 3a2 (col. 2, lines 58-60).

Delfosse discloses the claimed invention except for a socket that is hexagonal or torx shaped.

It is noted that Applicant discloses socket 520 of elongated member 420 to have any suitable shape (page 10, para [0020] of Applicant's specification).

Accordingly, it would have been an obvious matter of design choice to one of ordinary skill in the art at the invention was made to have constructed socket 3a2 of the Delfosse elongated member 3a with a cross-section having a hexagonal or torx shape, since applicant has not disclosed that this solves any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a socket. In re Dailey and Eilers, 149 USPQ 47 (1966).

Claims 5-7 and 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutter et al. (US 6,102,951) in view of McCue et al. (US 6,506,216).

Sutter et al. disclose a tibial plate 1, a base 30 extending from the plate, and a socket defined in the elongated member (7, 3, 2) wherein the socket includes a hexagonally-shaped portion and a screw-threaded portion. See previous discussion of Sutter et al. and marked up Fig. 4 on page 6 of this action.

Sutter et al. disclose all elements of the claimed invention except for: (1) first and second keel-like portions extending radially outwardly from base 30; and (2) an angle between the first and second keel-like portions of about 180 degrees.

McCue et al. teach providing wing elements or "keel-like portions" 26 on the keel or "base" 24 of a tray or plate 12 in the medial-lateral directions (i.e., angle of about 180 degrees) so as to provide both fixation and positional stability (Fig. 2 and col. 3, lines 29-36).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided first and second keel-like portions 26 on the base 30 of Sutter et al., as taught by McCue et al., to provide both fixation and positional stability to the implant of the combination of Sutter et al. and McCue et al.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sutter et al. (US 6,102,951) and McCue et al. (US 6,506,216), as applied to claim 17, further in view of Delfosse (US 5,658,341).

The combination of Sutter et al. and McCue et al. teaches all elements of the claimed invention except for a tibio-femoral insert coupled to the plate in the implant of the combination of Sutter et al. and McCue et al.

Delfosse teaches providing a "tibio-femoral" insert 2 coupled to a tibial plate to cooperate with (i.e., provide an articulating surface for) the femoral component of a total-knee prosthesis (Fig. 1 and col. 2, lines 34-40).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a tibio-femoral insert coupled to the plate in the implant of the combination of Sutter et al. and McCue et al., as taught by Delfosse, in order to mate the implant of the combination of Sutter et al., McCue et al. and Delfosse with the femoral component of a total knee prosthesis.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR
April 16, 2006

A handwritten signature in black ink, appearing to read "Anuradha Samana". The signature is written in a cursive, flowing style.